

REMARKS/ARGUMENTS

Claims 2-4, 6-7 and 9-10 remain in this application. Claims 1, 5, 8 and 11 have been cancelled. Claims 12 and 13 are new. Support for new claims 12 and 13 may be found in the specification on pages 8-9, paragraph [17] and page 14, paragraph [27]. The new claims were submitted in order to clarify the particular components of the claimed composition (claim 13) and to retain consistency between the method and the composition claims (claim 12). Claims 2-4, 6-7 and 9-10 have been amended in order to correct dependencies due to the cancellation of claims 1 and 8. No new matter has been added, thus the amendments and new claims do not affect the merits of the application.

The Examiner has indicated that claims 1-4, 6 and 7 are allowed.

The Rejections

1. Claim 8 is rejected under 35 USC 102(b) as being anticipated by Schraner et al. (hereinafter "Schraner").
2. Claim 8 is rejected under 35 USC 102(b) as being anticipated by Hockertz, S. (hereinafter "Hockertz").
3. Claims 8-9 are rejected under 35 USC 102(b) as being

anticipated by Kutilek, III et al. (hereinafter "Kutilek").

4. Claims 8 and 10 are rejected under 35 USC 102(e) as being anticipated by Squires.

All of rejections 1-4 applied to claims 8-10 are maintained over arguments presented in the response to the previous Office action, and all apparently for the same reason. The composition of claim 8 is comprised of two particular components: A) poultry feed and B) an *Echinacea* preparation in an amount effective for enhancing an immune response to an anticoccidial vaccine. In all of the Examiner's comments, the poultry feed component has been dismissed from consideration as it "only defines a recited intended use of the claimed composition" and it "does not define an additional composition component" (as claim 8 "can be read in such a way that the phrase 'poultry feed' modifies the amount of *Echinacea* that is present in the composition...").

Applicants respectfully traverse this reasoning. First, poultry feed is an important component of the composition. A reading of the specification, especially the Detailed Description of the Invention section starting on page 9, as well as the specific Examples, clearly describe the composition of the invention as poultry feed supplemented or mixed with the *Echinacea* preparation. Therefore, it is not in the spirit of the invention to eliminate the feed as a factor in the invention,

since it serves a very important purpose, i.e. it provides the means for the birds to ingest the *Echinacea* preparation. This function is not the same as an "intended use" as alleged by the Examiner; it has a separate and significant function independent of the *Echinacea* preparation. Second, it does define an additional component of the invention, for the same reason as discussed. Poultry feed serves a necessary and significant purpose, and how it serves merely as "modifying the amount of *Echinacea* ... present in the composition" is not understood. The amount of *Echinacea* needed is that amount needed in order to be effective for enhancing an immune response, and the presence of poultry feed does not determine that amount. Applicant respectfully urges that elimination of the consideration of poultry feed as a distinct component of the claimed composition is inappropriate at best. As pointed out in the response to the previous Office action, in order for a reference to be applied under § 102, that reference must meet each and every limitation of the claim to which it has been applied. It appears that the Examiner has arbitrarily dismissed poultry feed as a component in order to make the § 102 rejection fit!

For these reasons, it is respectfully requested that the Examiner reconsider the arguments presented in the previous response, without eliminating poultry feed from the composition.

For the Examiner's convenience, the rejections are repeated hereinbelow. It should also be noted that, with respect to the Squires reference which allegedly discloses "forms of poultry feed for administration to birds", "grain powder" and "cornmeal" are not particularly useful as poultry feeds.

1. Claim 8 has been rejected under 35 USC § 102(b) as being anticipated by Schraner. Schraner discloses the results of an investigation of the effects of the complex drug Influnx and an *Echinacea angustifolia* extract 1) on immunoglobulin and antibody synthesis in chickens immunized with human serum albumin and 2) on IgG synthesis in immunodeficient chickens. The preparations were administered orally, however, there is no indication of what was present in the composition administered besides the active test components. It is well-established that, in order for a reference to be properly applied under § 102, that reference must meet each and every limitation of the claims to which it has been applied. It is respectfully urged that the Schraner reference falls short of that requirement. First, claim 8 as amended is a composition comprising an *Echinacea* preparation and poultry feed. Schraner is completely silent with respect to the components of the preparation administered to the chickens, therefore one cannot merely assume that it is administered with poultry feed. Second, the claimed composition is effective for enhancing an

immune response to an anticoccidial vaccine. Schraner investigated the response to the combination of an *Echinacea* extract and administration of human serum albumin with respect to immunoglobulin and antibody synthesis, but reported no results. Only the administration of the complex drug resulted in a rise in serum immunoglobulin concentration and an increase in antibody levels. For these reasons, it is believed that the reference has been improperly applied under § 102, and it is requested that the rejection be withdrawn.

2. Claim 8 has been rejected under 35 USC § 102(b) as being anticipated by Hockertz. The Hockertz reference contains one mention of "a pressed echinaceae-preparation" in the abstract. Again, the requirements for application of a reference under § 102 is pointed out, and it is urged that Hockertz does not meet those requirements. First, the claimed composition is comprised of an *Echinacea* preparation and poultry feed. Hockertz is completely silent with respect to a composition and does not mention poultry or poultry feed under any circumstances. Second, the abstract appears to relate to the immunomodulator Uro-Vaxom (FEC) and its application to mouse macrophages (a mammalian system) to test their secretory, immuno-regulatory and cytotoxic functions. "In comparison to a pressed echinaceae-preparation, FEC activated mouse macrophages secrete Interleukin-6 and tumor-

necrosis-factor and kill protozoa, fungi and bacteria, with higher efficiency." A preparation having such a result in mice clearly does not anticipate a composition "effective for enhancing an immune response to an anticoccidial vaccine" in poultry. For these reasons, it is believed that the reference has been improperly applied under § 102, and it is requested that the rejection be withdrawn.

3. Claims 8-9 have been rejected under 35 USC § 102(b) as being anticipated by Kutilek. Kutilek discloses a dietary supplement comprising "an effective mixture of herbal extracts and powders, vitamins, minerals, amino acids, and various excipients" consumable as a tablet, capsule or beverage to treat human or animal subjects for bacterial, fungal and viral infections or other opportunistic infections in immunocompromised or immunosuppressed subjects. Again, the requirements for application of a reference under § 102 is pointed out, and it is urged that Kutelik does not meet those requirements. Kutelik does not teach an *Echinacea* preparation in combination with poultry feed, as is recited by amended claim 8. Moreover, Kutelik teaches administration of the dietary supplement by tablet, capsule or beverage, which is inconsistent with the poultry feed component of the instantly claimed composition. For this reason, it is believed that the reference has been

improperly applied under § 102, and it is requested that the rejection be withdrawn.

4. Claims 8 and 10 have been rejected under 35 USC § 102(e) as being anticipated by Squires. Squires discloses a composition used for topical treatment of herpes virus and other microbial infections. The composition "is a phytochemical concentrate which is combined and simultaneously or concurrently applied with a surfactant and a carrier, solvent or diluent to provide a microbicide medicinal solution." Again, the requirements for application of a reference under § 102 are pointed out, and it is urged that Squires does not meet those requirements. First, Squires discloses a composition which is utilized topically and does not contain poultry feed. The carriers pointed to are not conventional poultry feeds. Moreover, upon consideration of other components of the medicinal solution, i.e. surfactants, the composition would not be expected to be ingestible. Second, the medicinal solution would not be effective for enhancing an immune response to an anticoccidial vaccine. It is clear that the phytochemical concentrate is the active ingredient which directly attacks the particular microbial objective. The immune response is not regarded as important to the treatment and a vaccine is not even mentioned as a consideration in the objective of the treatment protocol. While it is recognized that inherency is an

issue which must be considered, it is urged that a composition which is effective as a topical treatment, acts directly on an infectious agent and is not ingestible does not anticipate a composition which is administered internally and acts upon the infectious agent by enhancing the immune system's response to a vaccine. For these reasons, it is believed that the reference has been improperly applied under § 102, and it is requested that the rejection be withdrawn.

In view of the amendments, response to the Examiner's comments and responses previously submitted, applicants believe that the application is now in condition for allowance. Accordingly, it is respectfully requested that the rejections be withdrawn and the application be allowed to issue. If any issues remain to be discussed, the Examiner is invited to telephone the undersigned at the number below.

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In view of the amendments, response to the Examiner's comments and responses previously submitted, applicants believe that the application is now in condition for allowance. Accordingly, it is respectfully requested that the rejections be withdrawn and the application be allowed to issue. If any issues remain to be discussed, the Examiner is invited to telephone the undersigned at the number below.

Respectfully submitted,

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